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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/189,130	11/10/98	HOUCK J	47.653.1

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HM12/0628

EXAMINER	
BORIN, M	
ART UNIT	PAPER NUMBER
1631	14

DATE MAILED: 06/28/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/189,130	Houck et al.
Examiner	**Group Art Unit**
M. Borin	1631

☒ Responsive to communication(s) filed on *Apr 10, 2000*.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1 and 4-31* is/are pending in the application.

Of the above, claim(s) *9-23* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1, 4-8, and 24-31* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Status of Claims

1. Acknowledgment is made of the amendment and Declaration filed 04/00. Claim 1 is amended. Claims 2-3 are canceled. Claims 24-31 are added. Claims 1,4-31 are pending. Claims 9-23 remain withdrawn from further consideration.

2. Claims 24-31 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. The claims are drawn to the same product as claimed in claim 1. Applicant is required to cancel the claims, or amend the claims to place the claims in proper dependent form, or rewrite the claims in independent form.

3. Upon reconsideration it was found necessary to apply a new ground of rejections under 35 U.S.C. 102/103. Applicants arguments with respect to rejection made under 35 U.S.C. 103 have been considered but are deemed moot in view of the new grounds of rejection.

4. Claim 1, 24-31 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C.103(a) as obvious over Kermode.

The instant claims are drawn to pharmaceutical composition comprising a formyl Met peptide having formula f-Met-Leu-Phe-Phe, wherein the active agent is taken in anti-inflammatory effective amount.

Kermode et al teach that chemotactic formyl Met peptides trigger biological responses of neutrophils which play a major role in body's defense mechanism against infectious microorganisms. In particular the reference teaches that formyl Met peptide, f-Met-Leu-Phe-Phe, is one of the most potent formyl Met peptides analogs. See p.276, first paragraph; Tables 1,2; Fig.2;p. 719. The formyl peptide is used in an aqueous solution, i.e., as a composition with a pharmaceutically acceptable carrier.

The referenced composition of f-Met-Leu-Phe-Phe anticipates the instantly claimed composition comprising f-Met-Leu-Phe-Phe. Although the reference does not specifically teach the "anti-inflammatory amount" of the peptide as instantly claimed, the instant claims are not limited to any particular concentration range, and the concentrations of the peptide in the referenced composition read on the instant broad claims. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure and composition, the properties applicant discloses and/or claims are necessarily present. In re Spada , 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Where the claimed and prior art products are identical or substantially identical in composition, a prima facie case of either anticipation or obviousness has been established. In re Best,195 USPQ 430, 433 (CCPA 1977).

Applicant argues that the prior art describes f-Met peptides as pro-inflammatory, while the "unexpected" property of the claimed composition is its anti-inflammatory effect. Note, however, the essential difference in the effect of a biological mediator (such as chemotactic f-Met peptide) when it is used alone as compared to its use in the presence of another pro-inflammatory agent.

Cellular response to f-Met peptides (which can be described as inflammatory response) is the same type of protective reaction which mediates response of the organism to a foreign infection. It is well known in the art that biological mediators such as chemotactic factors stimulate the migration of neutrophils from circulation into sites of infection or tissue damage. These mediators are also believed to increase cell adhesion to injured sites and to activate neutrophils to release toxic agents such as oxygen metabolites and proteases. Thus, in the presence of a provoked infection the response caused by f-Met peptides have protective, anti-inflammatory function. An example of an agent which, similarly to f-met peptides, can be either pro- or anti-inflammatory was given in the previous Office action: Effects of colony-stimulating factor (CSF) are similar to those of formyl peptides. See, e.g., Beaulieu et al., Wright et al.. CSF is one of the leading mediators of inflammation. See, e.g., al-Janadi et al. At the same time CSF is being used to treat inflammation. See, e.g., Burak et al.

Characteristically, in the Declaration filed 04/00 the effect of the claimed composition is demonstrated only as inhibitor of inflammatory effect caused by another f-Met peptide, fMLP. The absence in the Declaration of showing of the effect of fMLPP alone is not surprising because Kermode shows (Table 2) that fMLPP (the peptide of the claimed composition) is more potent chemotactic agent and stimulator of neutrophil degranulation than the fMLP (the peptide used as "pro-inflammatory" agent). One would expect that fMLPP, alone, would be at least as "pro-inflammatory" as fMLP.

The knowledge that formyl peptides stimulate various functions of neutrophils which constitute defense reaction to infectious microorganisms would be a sufficient motivation to an artisan

to apply such agent as a pharmaceutical under conditions when therapeutic stimulation of such defense reaction to infectious microorganisms is required.

5. Claims 1, 4-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kermode, as applied to claim 1 in the rejections above, and further in view of Goodman and Gilman.

In regard to routes of administration recited in claims 4-8, selection of a route of administration and appropriate carriers is an art-recognized result-effective variable which would have been routinely determined and optimized in the pharmaceutical art. See, e.g., Goodman and Gilman, p. 4-9, cited previously.

Conclusion.

6. No claims are allowed

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward can be reached on (703) 308-0254. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

June 23, 2000

mlb

MICHAEL BORIN, PH.D
PATENT EXAMINER